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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/688,246      | 10/16/2003  | Chenera Balan        | A-825               | 2469             |

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EXAMINER

BERNHARDT, EMILY B

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/688,246

Applicant(s)

BALAN ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 15-40 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13,15,16,18-22,24-39 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

In view of applicants' response filed 5/22/06 the following applies.

Applicants are reminded that the elected subject matter that is solely being examined is when compounds have Q3-Q6 as carbon and R4 is pyridine or dihydro or tetrahydro derivatives thereof as set forth in the previous action. Thus newly presented claims 17 and 23 are being held withdrawn as they do not read on elected subject matter. It is noted that claim 13 was inadvertently not included as pending in the previous action but was considered as part of the restriction requirement.

Claims 21,22,25-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Independent claim 21 lacks the definition for the "m" variable as far as the examiner can determine.

Claims 21,22,24-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new

set of claims recite subject matter broader than in the original disclosure. Note that the proviso present in the original disclosure for Q4/Q5 is not present in main claim 21.

Claims 1,3-10,13 (inadvertently omitted in previous action),15,16,18-22 and 24-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection of the previous action is repeated notwithstanding applicants' traverse. The relevant case law is not *Angstadt* relied on by applicants which dealt with an art area other than pharmaceuticals but rather *Surrey* previously cited as well as *In re Fisher* 166 USPQ 18 which emphasized that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved". Receptor binding is well-known to be structure-sensitive. Note the following quote from *PPG Indus. V. Guardian Indus. Corp* 37 USPQ2d 1618 at 1623: "In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. *See, e.g.*

, *In re Goodman* , 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.* , 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), *cert. denied* , 502 U.S. 856 (1991); *In re Vaeck* , 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation.” In the instant case the specification is at best an invitation to those skilled in the art to determine activity by using assays described therein but fails to clearly show what structure-activity requirements may exist for successful activity. With regard to the preparation of polysubstituted compounds as discussed in the previous action, the reaction scheme relied on in the specification in p.54 is of no help in the absence of reasonable assurance as to starting material sources or specific reaction conditions preparing necessary reactants. Note the following passage in *In re Howarth* (previously cited) at p.690: “Applicants' risk in leaving anything out of his application...burden rests upon applicant who chooses to rely upon general knowledge in art to render his disclosure enabling to establish that those of ordinary skill in the art can be expected to possess or know where to obtain this knowledge;” . Applicants’ additional traverse is not persuasive. Describing the invention as broadly as it is claimed does not necessarily enable one

how to make and use the invention. Literal support for the claims was also present in Surrey previously cited. If Surrey solely required literal support then the earlier Cauvallito decision (127 USPQ 202) would not have been heavily relied on as it was. Note the following quote taken from Cauvallito (regarding literal support at p.205, left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention." No such information is seen in the instant specification. With regard to structure-sensitivity note the following quote at p.206, left column: "On the other hand, wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried." Thus as long ago as the Cauvallito decision, the emphasis on the need for working examples **representative** of the claims' scope was a requirement for compliance with 35 USC 112, par.one in unpredictable arts and the requirement is still present- see MPEP 2164.02. Unpredictability entails structural sensitivity –a well known fact in drug design. Applicants urge they have provided 200+ examples but the examiner has already commented on the homogeneous nature of the substituents in these compounds. The fact that screening for vanilloid receptor binding may be routine does not necessarily preclude a finding of nonenablement

given the lack of any test data and scope of claims as previously discussed. Note that in *University of Rochester v. G.D.Searle & CO.* 68 USPQ2d 1424 at 1438 the screening for over 600 compounds was deemed to be undue. Applicants' scope far exceeds this number. Applicants state that their claims are "average in scope to typical issued pending claims" but this as discussed above and in the previous action is not the criterion for compliance with par.one.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3,4,7-10,13,15,16,18-22,24,26-30,36-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Sun for reasons of record. The species previously pointed out anticipate the added claims. Claim 13 dependent on claim 1 was inadvertently not included in the previous action.

Claims 5,6,11 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun for reasons of record. New claim 31 covers similar subject matter to that in claim 5 and thus embraces compounds that are obvious variants for the same reason as set forth in the previous action.

Applicants urge that they are entitled to benefit under 35 USC 119(e) filing date because there is "sufficient information to clearly allow persons of ordinary skill in the art to recognize that the inventor actually invented what was claimed."

However this is not the legal standard for obtaining 119 or 120 benefit. Lukach cited by applicants had to do with a subgenus being later claimed with no express description of such in an earlier application. There is ample case law which holds that broader subject matter presented in an application cannot be said to be adequately described in a priority application that describes only a part of the claimed subject matter. Note *In re Scheiber* 199 USPQ 782; *In re Gostelli* 10 USPQ2d 1614; *In re Chu* 36 USPQ 2d 1089. Also see, MPEP 706.02, section V, part (D) which stresses that the claims must be **fully** supported under the first paragraph of 35 USC 112. The claims remain not completely described in applicants' provisional application. As stated in the previous action the substituents for R<sup>4</sup> (which is also called R<sub>c</sub>) are not all completely described. Compare the list presented herein with that in the US provisional case. Clearly the list herein on the bottom of p.3 through p.4 is far broader. Also the scope at R<sup>e</sup> herein is not completely described in the earlier case. In the provisional case there is no mention of additional substitution with groups R<sup>g</sup>. Thus whenever R<sup>e</sup> appears herein it is broader than in the priority case. Also applicants employ R<sup>h</sup> herein while in the US provisional case, R<sup>a</sup> is employed. These variables are not identical in scope as R<sup>h</sup> is broader. These variables are also present in the myriad of functional groups for R<sup>5</sup>/R<sup>5'</sup>. Also while R<sup>g</sup> is seen in the earlier case it is only



used for the R1 definition. Applicants in the present claims have R<sup>g</sup> present as substituents in the many groups for R4/R5/R5'. In the provisional case R<sup>b</sup> is employed which is an entirely different set of choices. Also the species of claim 11 directed to the elected subject matter are not all described as set forth in the previous action.

Additionally, the claims do not comply with 35 USC 112, par. one for the reasons set forth in the above rejection.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 40 as admitted by applicants was taken from the US provisional case. While not new matter in the present case due to the "incorporation by reference" clause, it appears these species are not all described in the instant specification. If applicants disagree they should point to where such species can be found.

Claim 40 is objected to for containing nonelected subject matter but would otherwise be in condition for allowance as this claim does find descriptive support in the earlier case as applicants urge.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

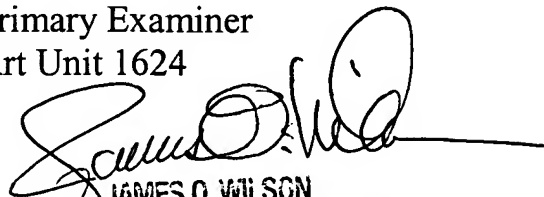
If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Art Unit: 1624

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Emily Bernhardt  
Primary Examiner  
Art Unit 1624



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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